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December 18, 1997

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
1242 Parklawn Dr., Room 1-23  
Rockville, MD 20857

ATTN: Comments on "Guide To Minimize Microbial Food Safety Hazards For Fresh Fruits and Vegetables"; Docket No.97N-0451.

Dear Sirs:

The Apple Hill Growers submit the following comments regarding the draft "Guide To Minimize Microbial Food Safety Hazards For Fresh Fruits and Vegetables".

For well over one-hundred years, El Dorado County growers have produced a diversity of fruit, vegetable and nut crops which have been served on America's tables from Northern California to the White House. The Apple Hill Growers are a proud component of California's agriculture industry, an industry responsible for the production of more than fifty percent of the nation's fruits and vegetables.

The Apple Hill Growers share a common goal with their fellow agriculturalists from California to New York: to produce a safe, wholesome, affordable supply of fresh fruits and vegetables to the American consumer. Historically, California growers have enjoyed overwhelming success in pursuit of this goal.

97N-0451

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During the past year, the Apple Hill Growers and the California agriculture industry have occupied a significant leadership role in addressing issues related to food borne illnesses associated with the consumption of fresh fruits and vegetables, and their processed by-products. Industry's proactive response, coupled with a progressive, problem solving approach on behalf of various local, state, and federal regulatory agencies have spawned partnership programs which serve to minimize the potential for microbial contamination of fresh fruits and vegetables and their by-products.

The Apple Hill Growers, in conjunction with the El Dorado County Department of Agriculture, the U.S Food and Drug Administration (FDA), California Department of Health Services (CDHS), California Department of Food and Agriculture (CDFA), and the University of California, developed a Quality Assurance Program (QAP) designed to enhance the safety of fresh, unpasteurized apple juice/cider. The Apple Hill QAP is a HACCP-based program of voluntary guidelines which address production of fresh apple juice/cider from the first cultural practices in the orchard through processing and final distribution; an integrated program from "bloom to bottle." Each element in the AH QAP was developed from the perspective of sound science integrated with the notion of what is feasible and doable in real world application.

Our concern with the process of the development of the draft "Guide To Minimizing Microbial Food Safety Hazards for Fresh Fruits and Vegetables" (guidance), is the apparent lack of close and direct industry participation characterized by the industry/government partnership programs so effectively developed in California. While consumers, industry, government, and the scientific community all share the common goal of enhanced food safety, the model of government/industry partnership programs represent the greatest opportunity to affect material, sustainable changes in agricultural production practices. We commend the FDA and various individual FDA representatives for the level of effort and commitment of time necessary to learn the practices and challenges of agricultural producers and processors.

Having directly participated in the development of the Apple Hill QAP, I believe the President's timetable for completion of the guidance is extraordinarily ambitious. In the absence of a current or impending food safety crisis, the long-term interests of the consumer and agricultural producer are



better served by a more realistic timetable for completion of the guidance. Additional time is also necessary to address some of the scientific gaps contained in the guidance, specifically those elements pertaining to water quality and the use of manure.

Modifying the timetable of the guidance would also allow further clarification of issues of concern to industry. The potential for the guidance to become regulation is a significant concern to the agriculture industry, particularly in California where producers operate under the most stringent regulatory environment in the U.S.. Current state and federal laws and regulations address some of the elements contained in the guidance. Agricultural producers are rightfully concerned about the potential burdens of duplicated regulation which may adversely affect their operations.

I urge the President and the FDA to carefully consider the development of the guidance, the nature of the process and its timetable. The Apple Hill Growers and California's agricultural producers have demonstrated a willingness and capability to adapt to a changing environment. America's producers of fresh fruits and vegetables are just as willing and capable, if given similar opportunity.

Thank you for the opportunity to comment.

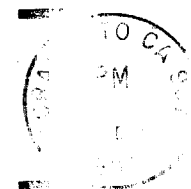
Sincerely,

A handwritten signature in black ink that reads 'Edio P. Delfino'.

Edio P. Delfino  
President,  
Apple Hill Growers



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